
SIRB
ALLIANCE

SIRB ALLIANCE
SIRBALLIANCE.ORG
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Introduction

Through consensus, we have built best practice solutions to use in the review process of NIH funded studies that uses sIRB.

Using these best practices eliminates the need for your IRB to read pages of guidance and then invent your own process. The documents are easy to use and can be applied immediately. Implementation of the sIRB Alliance best practices and information technology solutions guarantees a reduction on variations in sIRB review and enables institutions across the country to carry out the NIH's vision for a streamlined and efficient sIRB review model.

We have tested these best practices and had over 100 institutions provide feedback through surveys and working groups. The standardization of IRB review for NIH funded research is here and we encourage you to use this document and the other work we have completed in your interactions with participating sites.

The sIRB Alliance is made up of any institution who has contributed to building these standard practices.

Working groups drafted 3 versions for each solution, each with varying levels of flexibility of modification by participating sites. Working groups chose the two best solutions, which were then voted upon in a survey released to the wider IRB community. The sIRB Consensus survey was available for completion from 08/21/2018 till 09/30/2018. 63 participants from 57 unique Institutions responded to the survey. Out of the 57 Institutions, 25 are CTSA affiliated institutions. The solution with a majority of approving votes was selected as the chosen solution. This solution won majority of votes at **57%**. For more information, refer to our consensus document on the SIRB Alliance website.

To provide feedback, please head to www.sirballiance.org.

Addendum to SMART IRB Agreement
Flexible Terms

This document may be modifiable to any degree:

This Addendum ("Addendum") to the Master Common Reciprocal Institutional Review Board Authorization Agreement (Agreement) is intended to clarify certain terms of the Agreement that were intentionally designed to be flexible and adaptable to accommodate the needs of Reviewing IRBs and Relying Institutions for Research under Ceded Review.

The terms of the Agreement will apply to Ceded Review of the below named Research, as appended by this Addendum, in which [Reviewing IRB name] is serving as the Reviewing IRB.

This Addendum is intended to be consistent with and only to supplement the terms of the Agreement and is not intended to revise or modify any such terms. In the event of a conflict between the Agreement and this Addendum, the terms of the Agreement will control.

Unless otherwise defined herein, capitalized terms of Exhibit A of the Agreement apply to this Addendum. The Reviewing IRB and the Relying Institution may be referred individually as a "Party" and collectively, the "Parties."

STUDY NAME: [study title]
Reviewing IRB: **[Reviewing IRB name]**
Relying Institution: **[Relying Institution name]**

1. Standard Operating Procedures (SMART IRB Agreement Section 1.5)

The Parties will follow the SMART IRB SOPs with respect to the identified studies.

2. HIPAA Determinations (SMART IRB Agreement Sections 5.6 and 6.9)

Unless otherwise agreed, the Reviewing IRB will make determinations as required by and in compliance with the HIPAA Privacy Rule for use and disclosure of PHI for the Research, including waivers of, or alternations of authorizations.

3. Notification of Acceptance or Declination of Ceded Review (SMART IRB Agreement Section 3.4)

The Reviewing IRB will notify the Overall PI, the Site Investigator(s), and applicable Party(ies) that the study is accepted or declined for Ceded Review. Notification will be made through the SMART IRB Online Reliance System.When access to the SMART IRB Online Reliance System is not feasible for Site Investigator(s) and applicable Party(ies), the Overall PI will assist the Reviewing IRB in making this notification by another mechanism.

4. Notification of IRB Decisions, Changes, Lapses in Approval, Unanticipated Problems, Injuries, Complaints, and Serious and/or Continuing Noncompliance (SMART IRB Agreement Sections 5.9, 5.10, and 5.11)

The Reviewing IRB will directly notify the Overall PI, Site Investigator(s), and Relying Institution(s) of its determination(s) or review decision(s) regarding the study (e.g., approval, disapproval, required modifications), including, but not limited to:

- approved changes to the study;
- lapses in IRB approval and any applicable corrective action plans;

- review decisions, findings, and actions (including any suspension or termination of IRB approval) regarding unanticipated problems, subject injuries, and significant subject complaints in the study;
- findings and actions (including any suspension or termination of IRB approval) regarding serious or continuing or apparent serious or continuing noncompliance in the study and any required remediation actions.

5. HIPAA Authorization Language (SMART IRB Agreement Section 5.6.1.1, 5.6.1.2, 6.9.1 and 6.9.2)

Unless otherwise agreed, [t]he Reviewing IRB will make determinations as to what pathway under the HIPAA Privacy Rule (authorization / alteration or waiver of authorization /Limited Data Set) is applicable and required for the Relying Institution(s) to use/disclose PHI for the identified study(ies).

- If an authorization is required, the Reviewing IRB will determine the form of the authorization (e.g., incorporated into a consent form vs. freestanding) in collaboration with the Relying Institution(s).
- If alteration or waiver of authorization is requested the Reviewing IRB will perform the alteration/waiver analysis and be responsible for granting waivers or alterations of authorization
- If the Limited Data Set pathway is applicable, the Reviewing IRB will confirm that the PHI constitute a Limited Data Set and that a Data Use Agreement is or will be put into place.

Note: Apart from the determinations and actions referenced above, the Relying Institution(s) are responsible for performance of all of their other applicable HIPAA obligations in connection with the study(ies) (e.g., accounting of disclosures of PHI they make under a waiver of authorization).

6. Local Consideration (SMART IRB Agreement Section 6.4)

Relying Institution will provide local context information by completing the Local Context Form or other document provided by the Reviewing IRB and provide information about study specific issues as requested by the Reviewing IRB.

The Parties will work together to assure the Reviewing IRB has sufficient information to make Local Consideration determinations.

7. Conflict of Interest (SMART IRB Agreement Section 5.8 and 6.6)

Relying Institution will perform its own conflict of interest analysis under their relevant policy(ies) with respect to disclosure and management of their Research Personnel's conflicts of interest in connection with the identified study(ies). The Relying Institution will provide the

Reviewing IRB any resulting determinations, prohibitions and management plans that apply to Research under Ceded Review. The Reviewing IRB will, to the extent possible, accept the Relying Institution's management plan.

If the Relying Institution is limited in its ability to perform its own conflict of interest analysis, the Reviewing IRB will work with the Relying Institution to set-up a mechanism for collecting and evaluating conflict of interest related information from the sites research personnel.

8. Audits (SMART IRB Agreement Section 5.12 and 6.13)

Each Party will promptly notify the other Party of any audits, investigations or allegations related to the Research under Ceded Review that may have a material impact on the performance or review of the Research. The Parties will cooperate concerning any audit or investigation, including without limitation, providing Research records and related information, meeting with a Party's representatives, and assisting with the development and implementation of corrective action plans, as applicable.

9. Regulatory Reporting (SMART IRB Agreement Section 5.13, 5.13.1, 5.13.2. 5.13.3 and 6.14)

Reviewing IRB will draft and submit to federal regulatory oversight authorities any reports of unanticipated problems, serious or continuing noncompliance or suspension or termination of IRB approval that the IRB determines are required in connection with the identified study(ies). Reviewing IRB will provide the Relying Institution the opportunity (no fewer than five business days, if possible) to review and comment on the draft report(s) before submission to external recipients. The Relying Institution will promptly provide any comments on the draft report to the Reviewing IRB. The Reviewing IRB will consider such comments, but is under no obligation to incorporate them into the report. The Relying Institution will be responsible for notifying funding agencies, sponsors and other oversight authorities as applicable.

10. Congruence of federal grant (SMART IRB Agreement Section 5.15)

The Reviewing IRB will review the congruence of any federal grant application or proposal for human subject research with the Research submitted for Ceded Review, when required by federal regulations.

11. Fees (SMART IRB Agreement Section 2.3)

Unless otherwise agreed, the reviewing IRB and the Relying Institution(s) will enter a separate agreement or agreements under which the Relying Institution(s) will provide financial support to the Reviewing IRB for the costs of review of the identified study(ies).

12. Quality Assurance/ Quality Improvement program (SMART IRB Agreement Section 4.4)

Each Party will maintain, implement, or have access to a human subject research QA/QI process, function, program, or service that can conduct and report the results of for-cause and not-for-cause audits of the applicable institution's compliance with human subject protections and other relevant requirements. Any Party that does not have access to a QA/QI process or function must

have an alternate means of monitoring the conduct of Research as appropriate to ensure compliance. However, any Party agreeing to participate in a Ceded Review may agree between or among themselves to waive the requirement to have access to a QA/QI process, function, program or service or alternate means of monitoring with respect to the Research that is the subject of the Ceded Review.

13. Insurance (SMART IRB Agreement Section 4.10)

Each Party must maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its activities with respect to the identified study(ies), including coverage of its IRB/IRB members when acting as a Reviewing IRB. (State/federal agencies or instrumentalities of state/federal government may provide documentation of self-funded liability coverage or of reliance on applicable law providing immunity from or limiting liability.)
Each Party shall provide evidence of such insurance policy(ies) to the other Party upon request.

14. Claims (SMART IRB Agreement Section 4.11)

a. Non-public Institutions: Except to the extent a Party is a state institution subject to sovereign immunity laws (such institutions shall be governed by Subsection (b) below), each Party hereunder will be responsible ("Responsible Institution") for any third-party claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney's fees and court costs related thereto) ("Claims"), and shall defend, indemnify, and hold harmless, the other Party hereunder, its affiliatesand each of their trustees, directors, officers, representatives, faculty, IRB members, students, volunteers, employees, or other agents (the "Indemnified Parties") against claims brought against them, to the extent such Claims arise out of: (i) any breach of the Agreement or this Addendum by the Responsible Institution, or (ii) the negligent acts and omissions made by the Responsible Institution, Responsible Institution's IRB, as applicable, or any trustees, directors, officers, representatives, employees, faculty, IRB members, students, volunteers, or other agents of the Responsible Institution in the performance of the Agreement or this Addendum, including without limitation, negligent use or disclosure of any of the other Party's information. The Responsible Institution's obligations in this paragraph shall not apply to the extent that any such Claim results (in whole or in part) from the negligence, willful misconduct, recklessness or fraud of the other Party and/or any of its Indemnified Parties. Any Indemnified Party seeking indemnification shall (i) promptly notify the Responsible Institution in writing of any Claim, provided, however, that the failure to provide such notice shall not relieve the Responsible Institution of any of its indemnification obligations hereunder except to the extent that the Responsible Institution is prejudiced by such failure; (ii) at the Responsible Institution's sole cost and expense cooperate with all reasonable requests in the investigation and defense of such Claim; and (iii) permit the Responsible Institution to fully control the defense of such Claim, including, but not limited to, the selection of counsel and any settlement of such Claim. The Responsible Party shall have the right to settle Claims, at the Responsible Party's sole expense and in the Responsible

Party's sole discretion, provided that the Responsible Party shall not agree to any settlement which requires an admission of fault by any of the other Party's Indemnified Parties or contemplates any non-monetary damages affecting and of the other Party's Indemnified Parties without the consent of the other Party.

b. Public Institutions: To the extent permitted by law, each Party that is a state institution will be responsible ("Responsible Institution") for any third-party claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney's fees and court costs related thereto) ("Claims") brought against the other Party or its affiliates, and any of its trustees, directors, officers, representatives, faculty, IRB members, students, volunteers, employees, or other agents (the "Indeminfied Parties") to the extent such Claims arise out of (i) any breach of the Agreement or this Addendum by such Responsible Institution, or (ii) the negligent acts and omissions made by such Responsible Institution, its IRB, as applicable, or any of its trustees, directors, officers, representatives, employees, faculty, IRB members, students, volunteers, or other agents in their performance of the Agreement or this Addendum, including without limitation, negligent use or disclosure of any of the other Party's information. The Responsible Institution's obligations in this paragraph shall not apply in the event that any such Claim results in whole or in part from the negligence, willful misconduct, recklessness or fraud of the other Party and/or any of its Indemnified Parties. The Responsible Institution shall be liable to the other Party and/or the Indeminified Parties for reimbursement for such Claims. If a Responsible Institution, as a state/federal public institution that it is an instrumentality of a state/federal government, is further limited in substance by the applicable law of the state or federal jurisdiction in which such Responsible Institution serves as an instrumentality to the extent that such applicable law is designed to protect and limit the liability of such Responsible Institution as an instrumentality of such state/federal government, then the Responsible Institution's obligations to the other Party and/or its Indemnified Parties pursuant to this paragraph shall be limited to the extent of such applicable law. Notwithstanding any other terms or conditions of this Agreement, no state agency under the laws of its jurisdiction shall be deemed to waive any privileges or immunities that might be available to it under applicable law.

Any Indemnified Party seeking protection as provided in this section shall (i) promptly notify the Responsible Institution in writing of any Claim, provided, however, that the failure to provide such notice shall not relieve the Responsible Institution of any of its obligations hereunder except to the extent that the Responsible Institution is prejudiced by such failure; (ii) at the Responsible Institution's sole cost and expense cooperate with all reasonable requests in the investigation and defense of such Claim; and (iii) permit the Responsible Institution to fully control the defense of such Claim, including, but not limited to, the selection

of counsel and any settlement of such Claim. The Responsible Party shall have the right to settle Claims, at the Responsible Party's sole expense and in the Responsible Party's sole discretion, provided that the Responsible Party shall not agree to any settlement which requires an admission of fault by any of the other Party's Indemnified Parties or contemplates any non-monetary damages affecting any of the other Party's Indemnified Parties without the consent of the other Party.

This Addendum will be effective on the date of the last signature below.

[Reviewing IRB/Institution]	
[IO or designee] [title]	Date

[Relying Institution]	
[IO or designee] [title]	Date